

FIG. 1A

	-42 [†] to -30 [†]	-20 [†] to -12 [†]	1	7	10	17	24	31	38	45										
Day of Study				1	2	3	4	5	6	7										*
Week of Study																				
Month of Study									1	2	3	4	5	6	7	8	9	10	11	12
Surgery	X																			
Informed Consent		X																		
Randomize		X																		
Cyclophosphamide				X																
BCG					XA	XA	XB	XB	XC	XC				XC						
Vaccine			X		X	X	X	X	X	X				X						
History/Physical Exam	X		X		X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	*
Vital Signs	X		X		X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	*
Performance Status	X		X		X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	*
Routine Labs ^{††}	X		X		X	X	X	X	X	X	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	Xe	*
Pregnancy (HCG)	X																			
Hepatitis/HIV	X																			
Chest X-Ray											Xe	Xe			Xe	Xe				*
CT or MRI	X													Xe						.*

FIG. 1B

A ——— A

† This can be extended up to -56 days only if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

* History/Physical Exam, Vital Signs, Performance Status, Routine Labs, Chest X-Ray q2 months in year 2, q3 months in year 3, then q6 months through year 5; CT or MRI at 18, 24, and 36 months (chest x-ray omitted if CT/MRI scheduled)

XA 0.1 mL of a 1:10 dilution of Tice BCG (Tice-A) mixed with vaccine

XB 0.1 mL of a 1:100 dilution of Tice BCG (Tice-B) mixed with vaccine

XC 0.1 mL of a 1:1000 dilution of Tice BCG (Tice-C) mixed with vaccine

‡ This can be extended up to -34 days if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

‡‡ Routine Labs: hematology (CBC with differential, platelet count), BUN or creatinine, LDH, SGOT, alkaline phosphatase, electrolytes

<e End of Treatment Month